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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO
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103/29/99 03/29/99 1648

Q 2121-128PCT

EXAMINER

HILL, STEWART, FREASER & TEEBEE
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SCHETTNER, L.

ART UNIT

PAPER NUMBER

11

1648

DATE MAILED:

03/29/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 1/8/99.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 14-34 is/are pending in the application.

Of the above, claim(s) 18 & 27 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 14-17, 19-26 & 28-34 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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Applicant's election of the murabutide species in Paper No. 10 is acknowledged.

Accordingly, claims 18 and 27 are withdrawn from consideration as being drawn to a non-elected species. Moreover, claims 14-17, 19-26 and 28-34 will be read with the limitation of the elected species.

Claims 22 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 22 and 31 recites the broad recitation "a cytokine", and the claim also recites "interferon" which is the narrower statement of the range/limitation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-21, 25, 26, 28-30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreck et al.

Schreck et al. teach the importance of selecting adjuvants in potential vaccines against AIDS that do not induce activation of the cellular transcription factor nuclear factor- κ B (NF- κ B) since said (NF- κ B) activation has been strongly associated with enhanced replication of human immunodeficiency virus-type 1. More specifically, the reference teaches the administration of murabutide, both *in vitro* and *in vivo*, and find that the apyrogenic molecule induced either low activation levels or no activation of (NF- κ B). Please see under **Discussion** where the peptides have been utilized as adjuvants in experimental vaccines against HIV since strong activation of NF- κ B by vaccine components may contribute to enhanced viral replication rather than protective immunity.

Claims 14-21, 25, 26, 28-30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Masihi et al.

Essentially, Masihi et al. and Schreck et al. are cumulative with regard to methods of employing murabutide as an adjuvant in human clinical trials for AIDS.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-24 and 31-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Masihi et al..

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Masihi et al. teach as set forth above. Additionally, they teach the use of human recombinant GM-CSF in combination with zidovudine for treatment of AIDS in humans. It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered the murabutide in combination with another molecule such as a cytokine, GM-CSF or a protease inhibitor since said respective molecules are well known to be effective in the treatment of AIDS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

L.S.
Laurie Scheiner/LAS
March 26, 1999

Q
LM7.4.023
LAURIE SCHEINER
PRIMARY EXAMINER